



ZOFRAN LEGAL

Pursuing Justice For Zofran Birth Defect Victims

12 Core Facts About GlaxoSmithKline's Zofran And This Litigation

GlaxoSmithKline (GSK) manufactured *Zofran* (active ingredient: Ondansetron Hydrochloride)

In the 1980s GSK performed *Zofran* testing on rabbits and rodents. These tests showed [evidence of toxicity, malformations, and intrauterine deaths](#) in the animals

In 1991 The **Food & Drug Administration** (FDA) approved *Zofran* for sale in the United States to [patients who were suffering from extreme nausea](#) as a result of chemotherapy, radiation therapy, and for certain post operative procedures

The **FDA** [never approved *Zofran* as a drug for morning sickness](#) that was safe for pregnant women

GSK did not take *Zofran* through an approval process for the drug to be given to women for morning sickness. **GSK** commenced marketing *Zofran* from 1991 onward as a "safe" solution to vomiting, nausea, and morning sickness during pregnancy

In 1990, **GSK** was notified of 2 birth defects caused by mothers ingesting *Zofran* during the first trimester of pregnancy

By the year 2000, **GSK** was aware of [32 reported instances of a birth defect](#) attributed to *Zofran* ingestion by the birth mother for morning sickness. As of today there are over 200 reported defect cases

Several epidemiological studies were performed from the 1990's onward which may support a link between *Zofran* and child birth defects, in particular, [cleft palate, cleft lip, and congenital heart defects](#)

GSK has never performed any clinical trials on *Zofran* in pregnant women to gain **FDA** approval. **GSK** has [never modified the *Zofran* label](#) with warnings of child birth defects

In 2012, **GSK** settled claims brought by the US Government and [paid a record high \\$3 billion fine](#). This settlement included the allegations for the marketing of *Zofran* to pregnant women who were suffering from morning sickness, and included allegations of [paying kick-backs to physicians to prescribe *Zofran*](#) for morning sickness

GSK [continues to deny all allegations relating to *Zofran* causing birth defects](#). **GSK** has offered no warnings that the drug is unsafe for pregnant women and has not asked the **FDA** to do so either

[Personal injury lawsuits and class actions](#) are being filed against **GSK** as of February 2015

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